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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/662,783	09/12/00	SHIMKETS	R 15966-577 (C

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EXAMINER	
JIANG,D	
ART UNIT	PAPER NUMBER
1646	46

DATE MAILED: 07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/662,783	SHIMKETS ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, and 40, drawn to an isolated polypeptide, and a pharmaceutical composition thereof, classified in class 530, subclass 350.

II. Claims 6-15, and 64-65, drawn to an isolated nucleic acid molecule, a vector thereof, a host cell, and a method of recombinant expression of such, classified in class 435, subclass 69.1.

III. Claims 16-20, 42, and 46, drawn to an antibody to said polypeptide, and a pharmaceutical composition or a kit thereof, classified in class 530, subclass 387.9.

IV. Claim 21, drawn to a method for identifying a polypeptide in a sample with an antibody, classified in class 436, subclass 501.

V. Claim 22, drawn to a method for determining a nucleic acid molecule in a sample, classified in class 435, subclass 6.

VI. Claims 23-24, and 26-28, drawn to a method for identifying an agent binding to a polypeptide, and/or modulate an activity, classified in class 436, subclass 501.

VII. Claim 25, 29-32, 43-44, and 47, drawn to a method for modulating an activity of said polypeptide using a compound, and a therapeutic agent, and a pharmaceutical composition or a kit thereof, classification dependent upon species.

IX. Claims 33-34, 53, and 55-58, drawn to a method of treating or preventing a disorder or a pathological state, or promoting growth of cells in a mammal, or a subject with said polypeptide, classified in class 514, subclass 2.

IX. Claims 35-36, and 41 and 45, drawn to a method of treating or preventing a disorder with said nucleic acid in a subject, and a pharmaceutical composition or a kit thereof comprising the nucleic acid molecule, classified in class 54, subclass 44.

X. Claims 37-39, and 54, drawn to a method of treating or preventing a disorder, or a pathological state in a subject or a mammal with said antibody, classified in class 424, subclass 139.1.

XI. Claims 48 and 49, drawn to a method for screening for a modulator in a test animal (transgenic), classified in class 800, subclass 3.

XII. Claim 50, drawn to a modulator, classification dependent upon species.

XIII. Claim 51, drawn to a method for determining the presence of said polypeptide in a sample from a mammalian subject, classified in class 435, subclass 7.1.

XIV. Claim 52, drawn to a method for determining the presence of said nucleic acid in a sample, classified in class 435, subclass 6.

XV. Claims 59-63, drawn to a method of inhibiting growth of cells in a subject with a composition, classification dependent upon species.

The inventions are distinct, each from the other because:

The polypeptide of Invention I is related to the nucleic acid of Invention II by virtue of encoding same. The nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid molecules and the protein are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention II is related to the protein of Invention I as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the products as claimed may be isolated from their natural source or made by chemical peptide synthesis.

The polypeptide of Invention I is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are

distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Invention I and Inventions IV, VI, VIII, XI, and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the production of the antibodies of Invention III.

The product of Invention I and the methods of Inventions V, IX, and XIV are distinct and unrelated, wherein the product of Invention I can be neither made by nor used in the method of Invention V, IX, or XIV, and wherein each does not require the other.

The polypeptide of Invention I is distinct and unrelated from the products of Inventions VII and XII because they are physically and functionally distinct chemical entities which share neither structure nor function.

The product of Invention I and the methods of Inventions X and XV are distinct and unrelated, wherein the product of Invention I can be neither made by nor used in the method of Invention X or XV, and wherein each does not require the other.

The nucleic acid of Invention II is distinct and unrelated from the products of Inventions III, VII and XII because they are physically and functionally distinct chemical entities which share neither structure nor function.

The product of Invention II and the methods of Inventions IV, VI, VIII, XI, and XIII are distinct and unrelated, wherein the product of Invention I can be neither made by nor used in the method of Invention IV, VI, VIII, XI, and XIII, and wherein each does not require the other.

Invention II and Inventions V, IX, and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the production of the polypeptide of Invention I.

The product of Invention II and the methods of Inventions X and XV are distinct and unrelated, wherein the product of Invention I can be neither made by nor used in the method of Invention XI or XVI, and wherein each does not require the other.

The antibody Invention III and the methods Inventions IV, X and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody product as claimed may be used for the purification of the polypeptide of Invention I.

The product of Invention III and the methods of Inventions VI, VIII, XI, and XIII are distinct and unrelated, wherein the product of Invention I can be neither made by nor used in the method of Invention VI, VIII, XI, and XIII and wherein each does not require the other.

The product of Invention III and the methods of Inventions V, IX, and XIV are distinct and unrelated, wherein the product of Invention III can be neither made by nor used in the method of Invention V, IX, or XIV, and wherein each does not require the other.

The product of Invention III is distinct and unrelated from the products of Inventions VII and XII because they are physically and functionally distinct chemical entities which share neither structure nor function.

Inventions IV, X and XV are drawn to methods of using said antibody for treating or diagnosing diseases, wherein each of the methods is distinct as each requires independent objects, and starting elements, such as a subject, or a sample, which are physically and functionally distinct, and method steps involved are different, such that they require non-coextensive searches.

Inventions V, IX, and XIV are drawn to methods of using said nucleic acid for treating or diagnosing diseases, wherein each of the methods is distinct as each requires independent objects, and starting elements, such as a subject, or a sample, which are physically and functionally distinct, and method steps involved are different, such that they require non-coextensive searches.

Inventions VI, VIII, XI, and XIII are drawn to methods of using said polypeptide for identifying an agent, treating or diagnosing diseases, or generating transgenic animals, wherein each

of the methods is distinct as each requires independent objects, and starting elements, such as a subject, a transgenic animal, or a sample, which are physically and functionally distinct, and method steps involved are different, such that they require non-coextensive searches.

Inventions IV, X, XV, Inventions V, IX, XIV, and Inventions VI, VIII, XI, and XIII are distinct and unrelated, wherein each does not require the other.

The product of Invention VII is distinct and unrelated from the product of Invention XII because they are physically and functionally distinct chemical entities which share neither structure nor function.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. Furthermore, if applicants elect any one of the groups set forth above, further restriction is required under 35 U.S.C. 121:

A. One specific amino acid sequence with SEQ ID NO:, i.e. SEQ ID NO:2 or 4, and

B. One specific nucleic acid sequence with SEQ ID NO:, i.e. SEQ ID NO:1 or 3, which encodes the elected amino acid sequence in Group A, if Group II, V, IX or XIV is elected.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs, is a unique sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must elect one from Groups I - XVI, one from Group A, and/or one from Group B, even though the requirement is traversed. Applicant is advised that neither I - XVI nor A and B are species election requirements; rather, each of I – XVI, A and B is a restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

LORRAINE SPECTOR
PRIMARY EXAMINER

DJ
7/10/01